

# APPENDIX B

## APPENDIX B

### STATE-LAW VARIATIONS – SUBSTANTIVE CLAIMS ASSERTED BY PROPOSED MEDICAL MONITORING REMEDY CLASS

The table below identifies some of the variations in state laws governing negligence, negligence *per se*, negligent misrepresentation, manufacturing defect, failure to warn and state product liability act claims. These are the substantive causes of action underlying Plaintiffs’ proposed medical monitoring Remedy Class that are not addressed in other appendices.<sup>1</sup> The variations set forth in the table below are the very sorts of differences in state law that have led to the denial of class certification in the following cases (and numerous others):

- *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) (“The law of negligence, including subsidiary concepts such as **duty of care, foreseeability, and proximate cause**” differs among the states in “important” ways that preclude nationwide class certification.) (emphasis added);
- *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 743 n.15 (5th Cir. 1996) (nationwide class asserting strict liability product-liability claims improper because “[p]roducts liability law . . . differs among states. **Some states do not recognize strict liability . . . Some have adopted RESTATEMENT (SECOND) OF TORTS § 402A. . . . Among the states that have adopted the Restatement, there are variations.**”) (emphases added);
- *Carpenter v. BMW of N. Am., Inc.*, No. 99-CV-214, 1999 U.S. Dist. LEXIS 9272, at \*18 (E.D. Pa. June 21, 1999) (denying motion for class certification; “As for

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<sup>1</sup> Variations in state laws with respect to the Medical Monitoring Plaintiffs’ claims for breach of warranty and fraud are described in detail in Appendix F, G, H to Defendants’ Opposition to Plaintiffs’ Motion for Class Certification of Consumer Economic Loss Classes.

negligent misrepresentation . . . the elements needed to establish negligent misrepresentation will vary among the 50 states, **with some states not even recognizing such a claim.**”) (emphasis added).

Claim	Sample of State-Law Variations
Negligence	<ul style="list-style-type: none"> <li> <b>Whether foreseeability is an element of the duty of care.</b> There is no uniform approach to this question. In Colorado, for example, foreseeability is “an integral element” of the duty of care assessment. <i>Westin Operator, LLC v. Groh</i>, 347 P.3d 606, 613-14, n.5 (Colo. 2015). By contrast, at least two states in the proposed negligence subclass have adopted the Restatement (Third) of Torts: Liability for Physical Harm § 7(a), which eliminates foreseeability from the duty analysis and presumes that parties have “a duty to exercise reasonable care when the actor’s conduct creates a risk of physical harm.” <i>Thompson v. Kaczinski</i>, 774 N.W.2d 829, 835 (Iowa 2009); <i>Rodriguez v. Del Sol Shopping Ctr. Assocs., L.P.</i>, 326 P.3d 465, 467 (N.M. 2014) (“[W]e clarify and expressly hold that foreseeability is not a factor for courts to consider when determining the existence of a duty, or when deciding to limit or eliminate an existing duty in a particular class of cases.”). </li> <li> <b>Assumption of Risk.</b> States employ a variety of tests to determine whether a plaintiff has assumed a risk of harm. For example, in Georgia, “a defendant asserting an assumption of the risk defense must establish that the plaintiff (1) had actual knowledge of the danger; (2) understood and appreciated the risks associated with such danger; and (3) voluntarily exposed himself to those risks.” <i>Muldovan v. McEachern</i>, 523 S.E.2d 566, 569 (Ga. 1999). If successful, the defense is a complete bar to recovery. <i>Id.</i> By contrast, California distinguishes between primary assumption of risk—“those instances in which the assumption of risk doctrine embodies a legal conclusion that there is ‘no duty’ on the part of the defendant to protect the plaintiff from a particular risk”—and secondary assumption of risk—where “the defendant does owe a duty of care to the plaintiff but the plaintiff knowingly encounters a risk of injury caused by the defendant’s breach of that duty.” <i>Cheong v. Antablin</i>, 16 Cal. 4th 1063, 1067-68, 946 P.2d 817, 820 (1997). While primary assumption of risk is a complete bar to recovery, secondary assumption of risk merely affects the apportionment of fault. <i>Id.</i> By further contrast, other states have abolished the defense or subsumed it entirely under their comparative fault systems. <i>E.g.</i>, <i>Rountree v. Boise Baseball, LLC</i>, 296 P.3d 373, 381 (Idaho 2013) (holding that “the use of assumption of risk as a defense shall have no legal effect . . . ‘issues should be discussed in terms of contributory negligence, not assumption of risk, and applied </li> </ul>

Claim	Sample of State-Law Variations
	<p>accordingly under our comparative negligence laws”) (citations omitted).</p> <ul style="list-style-type: none"> <li>• <b><i>Standard for proportional responsibility.</i></b> State negligence laws also vary significantly with respect to whether a plaintiff’s own contributory negligence bars him/her from recovering. For example, North Carolina applies contributory negligence principles and prohibits recovery entirely in some circumstances. <i>See Muteff v. Invacare Corp.</i>, 721 S.E.2d 379, 384 (N.C. Ct. App. 2012) (holding that North Carolina “is a contributory negligence state” and therefore “[i]f a defendant can prove negligence – absent a finding of gross negligence on the part of the defendant – and proximate cause on the part of a plaintiff, that plaintiff will be completely barred from recovery”). By contrast, Alaska has adopted a pure comparative negligence system that allows a claimant to recover against a party for that party’s assigned degree of fault. <i>See Alaska Stat. Ann. § 09.17.080</i>. And by further contrast, Arkansas uses a modified comparative negligence system, whereby a claimant’s recovery is barred only if the claimant’s own fault is “equal to or greater in degree” than the fault of the party from whom he or she is seeking to recover. <i>See Ark. Code Ann. § 16-64-122(b)(2)</i>.</li> </ul>
Negligence <i>per se</i>	<ul style="list-style-type: none"> <li>• <b><i>Whether a negligence per se claim may be based on a statute that does not expressly provide for a civil remedy.</i></b> “[S]ome states do not limit negligence per se claims to statutes that contain express private right of actions,” while others do. <i>In re Valsartan, Losartan, &amp; Irbesartan Prods. Liab. Litig.</i>, MDL 2875, 2021 WL 307486, at *8 (D.N.J. Jan. 29, 2021). For example, under Georgia and Florida law, “claims for negligence per se . . . fail ‘if the statute or regulation establishing the claimed legal duty does not provide a cause of action for damages for its violation.’” <i>Green v. Medtronic, Inc.</i>, No. 1:19-CV-3242-TWT, 2020 WL 4577713, at *4 (N.D. Ga. May 1, 2020) (quoting <i>Scoggins v. Floyd Healthcare Mgmt. Inc.</i>, No. 4:14-CV-00274-HLM-WEJ, 2016 WL 11544774, at *41 (N.D. Ga. June 10, 2016)); <i>Sorenson v. Pro. Compounding Pharmacists of W. Pa., Inc.</i>, 191 So. 3d 929, 934 (Fla. Dist. Ct. App. 2016) (finding no private cause of action for negligence <i>per se</i> absent statutory language “suggesting an intent to create a private cause of action for the violation of its requirements”). However, other states (e.g., Alabama), do not impose such a limitation. <i>See In re Valsartan, Losartan, &amp; Irbesartan Prods. Liab. Litig.</i>, MDL 2875, 2021 WL 307486, at *8 (D.N.J. Jan. 29, 2021) (citation omitted).</li> <li>• <b><i>Whether noncompliance with a statute is conclusive proof or merely evidence of negligence.</i></b> Several states do not treat the violation of a</li> </ul>

Claim	Sample of State-Law Variations
	<p>statute or regulation as conclusive proof of negligence, but merely as evidence relevant to negligence. <i>See, e.g., Joseph v. Bozzuto Mgmt. Co.</i>, 173 Md. App. 305, 329, 918 A.2d 1230, 1243 (2007) (“Maryland is among the minority of states that treat the violation [of a statute or regulation] simply as evidence of negligence” not as negligence <i>per se</i>); <i>Camara v. Aagsalud</i>, 67 Haw. 212, 218, 685 P.2d 794, 798 (1984) (“noncompliance with an established statutory standard is not necessarily conclusive on the issue of negligence, but is merely evidence of negligence”); <i>Gillingham v. Stephenson</i>, 209 W. Va. 741, 746, 551 S.E.2d 663, 668 (2001) (“[v]iolation of a statute is prima facie evidence of negligence” that can be rebutted by defendant). However, in other states, such as Minnesota, “violation of [a] statute constitutes conclusive evidence of negligence.” <i>Pigman v. Nott</i>, 305 Minn. 512, 513, 233 N.W.2d 287, 288 (Minn. 1975).</p> <ul style="list-style-type: none"> <li>• <b><i>Whether a negligence per se claim can be based on violations of the FDCA or analogous state laws.</i></b> A number of states, such as Alaska and Colorado, have held that the Food, Drug and Cosmetics Act (“FDCA”) cannot be the basis for a negligence <i>per se</i> claim. <i>See, e.g., Shanks v. Upjohn Co.</i>, 835 P.2d 1189, 1200-1201 (Alaska 1992) (holding that misbranding provisions of Alaska’s analogous FDCA cannot support a viable negligence <i>per se</i> claim); <i>Liby v. City Park Fam.</i>, No. 2011-CV-436, 2012 Colo. Dist. LEXIS 781, at *12 (D. Colo. Feb. 27, 2012) (“[T]he FDCA and its underlying regulations cannot serve as a basis for a negligence per se claim.”). And in Kentucky, negligence <i>per se</i> applies only to violations of Kentucky law, not federal law. <i>St. Luke Hosp., Inc. v. Straub</i>, 354 S.W.3d 529, 534 (Ky. 2011) (“Violations of federal laws and regulations and the laws of other states do not create a cause of action based on KRS 446.070.14,” which codifies the negligence <i>per se</i> claim). However, other states, including Pennsylvania, have held that violations of the FDCA can support a claim for negligence <i>per se</i>. <i>See Polt v. Sandoz, Inc.</i>, 462 F. Supp. 3d 557, 569 (E.D. Pa. 2020) (Pennsylvania law) (citing <i>Cabiroy v. Scipione</i>, 2001 PA Super 29, 767 A.2d 1078, 1081 (Pa. Super. Ct. 2001)).</li> </ul>
Negligent misrepresentation	<ul style="list-style-type: none"> <li>• <b><i>Is negligent misrepresentation a recognized cause of action?</i></b> While some states (e.g., Ohio and Kentucky) recognize negligent misrepresentation as a distinct tort, <i>see, e.g., Moffitt v. Auberle</i>, 854 N.E.2d 222, 224 (Ohio Ct. App. 2006); <i>Presnell Constr. Managers, Inc. v. EH Constr., LLC</i>, 134 S.W.3d 575, 582 (Ky. 2004), other states (e.g., Arkansas) do not, <i>see Bodtke v. Stryker Corp.</i>, No. 4:10CV1148 JMM, 2011 WL 223013, at *3 (E.D. Ark. Jan. 24, 2011) (“The Arkansas Supreme Court does not recognize the tort of negligent misrepresentation.”).</li> </ul>

Claim	Sample of State-Law Variations
	<ul style="list-style-type: none"> <li>• <b>Whether a privity or privity-like relationship between the parties is required.</b> “[U]nder New York’s law for negligent misrepresentation a plaintiff is required to show either privity of contract or a relationship approaching privity, while Texas does not require such a showing.” <i>In re Valsartan, Losartan, &amp; Irbesartan Prods. Liab. Litig.</i>, MDL 2875, 2021 WL 307486, at *8 (D.N.J. Jan. 29, 2021) (comparing <i>Parrott v. Coopers &amp; Lybrand LLP</i>, 95 N.Y.2d 479, 483 (N.Y. 2000) with <i>Averitt v. PriceWaterhouseCoopers L.L.P.</i>, 89 S.W.3d 330, 335 (Tex. App. 2002)); <i>see also Palmer-Donavin Mfg. Co. v. Rheem Sales Co.</i>, No. 2:14-cv-91, 2014 WL 2767665, at *8 (S.D. Ohio June 18, 2014) (requiring special relationship between the parties to state a negligent misrepresentation claim under Ohio law).</li> </ul>
Products Liability – Manufacturing Defect	<ul style="list-style-type: none"> <li>• <b>Whether the defect must be unreasonably dangerous.</b> Pennsylvania requires a strict liability plaintiff to prove, consistent with Restatement (Second) of Torts Section 402A, that a product is both “defective” and “unreasonably dangerous.” <i>Tincher v. Omega Flex, Inc.</i>, 104 A.3d 328, 400 (Pa. 2014) (stating that “the notion of ‘defective condition unreasonably dangerous’ is the normative principle of the strict liability cause of action” under Pennsylvania law). By contrast, California does not require a plaintiff to prove that the product was “unreasonably dangerous.” <i>Brown v. Superior Court</i>, 44 Cal. 3d 1049, 1057, 751 P.2d 470, 474 (1988). Other states have adopted the standard set out in Section 402A, like Pennsylvania, but added additional elements. <i>See, e.g., Kohler v. Ford Motor Co.</i>, 187 Neb. 428, 191 N.W.2d 601, 606 (1971) (Nebraska) (requiring a strict liability plaintiff to show he was “rightfully using that product”).</li> <li>• <b>Assumption of Risk and Standard for Proportional Responsibility.</b> Assumption of risk is a complete defense to a product liability claim in some states. <i>E.g.</i>, S.C. Code Ann. § 15-73-20 (“If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery”). In others, as noted above, the assumption of risk doctrine has been subsumed into a comparative fault analysis. <i>See Jimenez v. Sears, Roebuck &amp; Co.</i>, 183 Ariz. 399, 405, 904 P.2d 861, 867 (1995) (noting that “[d]espite some theoretical criticism of applying comparative fault to strict liability claims, many courts have used comparative fault in strict products liability cases”).</li> </ul>
Failure to Warn	<ul style="list-style-type: none"> <li>• <b>Strict liability versus negligence.</b> “[S]ome states categorically reject strict liability failure to warn claims,” such as Virginia, Pennsylvania, North Carolina, Massachusetts and Delaware. <i>In re Valsartan, Losartan, &amp; Irbesartan Prods. Liab. Litig.</i>, MDL 2875, 2021 WL 307486, at *20 (D.N.J. Jan. 29, 2021) (dismissing claims for strict</li> </ul>

Claim	Sample of State-Law Variations
	<p>liability failure to warn that arise under the laws of Virginia, Pennsylvania, North Carolina, Massachusetts and Delaware with prejudice). Other states, such as California, recognize such a cause of action. <i>See Snyder v. Does</i>, No. 4:20-cv-08419-KAW, 2021 U.S. Dist. LEXIS 174699, at *13 (N.D. Cal. Sept. 14, 2021) (California recognizes a claim for strict liability failure to warn).</p> <ul style="list-style-type: none"> <li>• <b><i>Whether the defect must be unreasonably dangerous.</i></b> As with the manufacturing defect claim, states differ on whether a claim for strict liability failure to warn requires a showing that the product was “unreasonably dangerous.” <i>See e.g., Wegmann v. Ethicon, Inc.</i>, No. 4:20-CV-00704 JAR, 2020 WL 5814475, at *9 (E.D. Mo. Sept. 30, 2020), <i>reconsideration denied</i>, No. 4:20-CV-00704 JAR, 2020 WL 6680893 (E.D. Mo. Nov. 12, 2020) (under Missouri law, plaintiff must show that “the product was unreasonably dangerous at the time of sale”); <i>Brown v. Superior Court</i>, 44 Cal. 3d 1049, 1057, 751 P.2d 470, 474 (1988) (noting that “[i]n <i>Cronin</i>, we rejected the requirement of section 402A that the defect in a product must be ‘unreasonably dangerous’ to the consumer in order to invoke strict liability”).</li> <li>• <b><i>Whether states recognize the heeding presumption.</i></b> States differ on whether they recognize a heeding presumption, which creates a rebuttable presumption that a plaintiff would have followed an adequate warning had one been provided. <i>Norwood v. Raytheon Co.</i>, 237 F.R.D. 581, 599 (W.D. Tex. 2006) (comparing Texas, which recognizes such a presumption, with New York, which does not) (citations omitted); <i>see also Barnhill v. Teva Pharms. USA, Inc.</i>, 819 F. Supp. 2d 1254, 1262 (S.D. Ala. 2011) (“Alabama courts have not recognized such a [heeding] presumption”) (citing <i>Deere &amp; Co. v. Grose</i>, 586 So. 2d 196, 198 (Ala. 1991)).</li> <li>• <b><i>Whether states recognize a post-sale duty to warn.</i></b> States differ on whether they recognize a post-sale duty to warn consumers of purported dangers that become apparent after sale. For example, in New York, “the post-sale duty of a manufacturer to warn involves the weighing of a number of factors including the degree of danger the problem involves, the number of reported incidents, the burden of providing the warning, as well as the burden and/or ability to track a product post-sale.” <i>Liriano v. Hobart Corp.</i>, 92 N.Y.2d 232, 240, 700 N.E.2d 303, 307 (1998). Alaska employs a similar test, but only “when the danger is potentially life-threatening.” <i>Jones v. Bowie Indus., Inc.</i>, 282 P.3d 316, 335 (Alaska 2012). By contrast, Minnesota has adopted the reasonableness standard set out in the Restatement (Third) of Torts: Products Liability, Section 10(b)(1). <i>Great N. Ins. Co. v. Honeywell Int’l, Inc.</i>, 911 N.W.2d 510, 520 (Minn. 2018) (post-sale</li> </ul>



Claim	Sample of State-Law Variations
	<p>duty to warn exists “if a reasonable person in the seller’s position would provide such a warning”). At the other end of the spectrum are various other states, such as Delaware and South Carolina, which have not recognized a post-sale duty to warn. <i>See Smith v. DaimlerChrysler Corp.</i>, No. CIV.A. 94C-12-002JEB, 2002 WL 31814534, at *5 (Del. Super. Ct. Nov. 20, 2002); <i>Davenport v. Goodyear Dunlop Tires N. Am., Ltd.</i>, No. 1:15-CV-03752-JMC, 2018 WL 1166091, at *3 (D.S.C. Mar. 6, 2018).</p>
State Product Liability Acts	<ul style="list-style-type: none"> <li>• <b><i>Whether the defect must be unreasonably dangerous.</i></b> The states that have codified their product liability laws by statute vary as to whether unreasonably dangerous is a required element of a strict liability claim. Connecticut has adopted Restatement (Second) of Torts Section 402A, and requires that a plaintiff prove that a product is both “defective” and “unreasonably dangerous,” meaning “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” <i>Metro. Prop. &amp; Cas. Ins. Co. v. Deere &amp; Co.</i>, 302 Conn. 123, 131, 25 A.3d 571 (2011). By contrast, the Louisiana Product Liability Act combines the “defective” and “unreasonably dangerous” elements into a single test, and provides separate unreasonably dangerous standards for manufacturing defects, design defects and inadequate warning. <i>See Sketchler v. Hernandez</i>, 2020-0292 (La. App. 1 Cir. 5/19/21), 326 So. 3d 912, 917 (“A plaintiff in a products liability action must prove that the product was defective, i.e., unreasonably dangerous to normal use”); <i>see also</i> La. Rev. Stat. 9:2800.54(b), 9:2800.55, 9:2800.57.</li> <li>• <b><i>Heeding presumption.</i></b> States with product liability statutes also vary with regard to heeding presumptions. For example, Connecticut, Tennessee and Washington do not recognize a heeding presumption—i.e., it is the plaintiff’s burden to “prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the [plaintiff] would not have suffered the harm.” Conn. Gen. Stat. Ann. § 52-572q(d); <i>see also Payne v. Novartis Pharm. Corp.</i>, 767 F.3d 526, 533 (6th Cir. 2014) (describing the various forms of heeding presumption adopted by various states and noting “Tennessee has not adopted any of these presumptions”); <i>Luttrell v. Novartis Pharms. Corp.</i>, 894 F. Supp. 2d 1324, 1345, n.16 (E.D. Wash. 2012) (noting that the “read and heed” presumption is not recognized by Washington law), <i>aff’d</i>, 555 F. App’x 710 (9th Cir. 2014). By contrast, Indiana and Kentucky recognize the heeding presumption, but provide that the presumption “may be rebutted with evidence that an adequate warning would not have been heeded.” <i>In re Fosamax Prods. Liab. Litig.</i>, 688 F. Supp. 2d 259, 266 (S.D.N.Y. 2010) (applying Indiana law); <i>Bloxom</i></li> </ul>



Claim	Sample of State-Law Variations
	<p><i>v. Bloxom</i>, 512 So. 2d 839, 850 (La. 1987) (“The presumption may, however, be rebutted if the manufacturer produces contrary evidence which persuades the trier of fact that an adequate warning or instruction would have been futile under the circumstances”).</p> <ul style="list-style-type: none"> <li>• <b><i>Standard for proportional responsibility.</i></b> The states that have codified their product liability laws by statute also vary with respect to the effect of a plaintiff’s own contributory negligence on his/her recovery. For example, Kentucky has adopted a pure comparative negligence system for both product liability and other tort claims. Ky. Rev. Stat. Ann. § 411.182 (West); <i>see also Owens Corning Fiberglas Corp. v. Parrish</i>, 58 S.W.3d 467, 475 (Ky. 2001), <i>as modified</i> (Nov. 7, 2001) (holding that a plaintiff’s comparative fault in a product liability claim is not limited to product misuse). By contrast, Indiana uses a modified comparative negligence system, whereby a claimant’s recovery is barred only if the claimant’s own fault is “greater than the fault of all persons whose fault proximately contributed to the claimant’s damages,” Ind. Code Ann. § 34-51-2-6, and otherwise is reduced in proportion to the claimant’s fault, Ind. Code Ann. § 34-51-2-5.</li> </ul>